

Alternate Language for FRN

Alternate text for FRN to implement the ACMUI's recommendation to remove the requirement for a preceptor statement from criteria for NRC or Agreement State recognition of specialty board certifications.

Changes to Discussion: Under the heading Certification Pathway, remove the phrase "obtaining a written preceptor statement" from the third sentence.

Addition to Discussion: Insert the following between paragraphs 3 & 4 under the heading Certification Pathway.

During the tele-conference with ACMUI, conducted on July 17, 2003, ACMUI members continued to voice concern about having recognition of boards certifications conditioned on requiring candidates for certification to obtain written attestation of competency signed by a preceptor. The ACMUI recommended that if the Commission still maintained that it was necessary to include a preceptor statement for all authorized positions named in Part 35, this requirement be separated from the criteria for recognition of board certifications, as well as the alternative pathway. Agreement State representatives participating in the tele-conference agreed with this recommendation. In a letter, dated July 23, 2003, Dr. Manuel Cerqueira, Chair of the ACMUI, restated the ACMUI's recommendation that the requirements for a preceptor statement be removed from the certification pathway; however, if the Commission still felt it necessary to include a preceptor statement for all authorized positions named in Part 35, the ACMUI recommended that this requirement be separated from the board certification pathway and the alternate pathway and specified separately as a new paragraph in each training section. The NRC has adopted ACMUI's recommendation because it retains the requirement of obtaining preceptor statements in order to satisfy the training required by both the board certification and alternate pathways, while placing the responsibility upon the individual seeking authorized status to obtain the preceptor statement.

Changes to Section by Section: Substitute the following at appropriate points in the “Section by Section Analysis.”

Section 35.50 - Training for Radiation Safety Officer.

This section would be amended to modify the requirements that must be met as part of a specialty board certification process for the specialty board to be recognized by the Commission or an Agreement State. Instead of requiring that the certification process include the same criteria as the alternate pathway, paragraph (a) would be amended to provide separate requirements for a specialty board’s certification process. This process would include a requirement to pass an examination, administered by diplomates of the specialty board, which would evaluate knowledge and competency areas that are important to functioning as a radiation safety officer. The requirement for obtaining a preceptor statement would be removed from the requirements for recognition of specialty board certifications but would, instead, apply to each individual seeking recognition as a radiation safety officer. Paragraph (c) would be modified to allow medical physicists to serve as RSOs if they are certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State. A new paragraph (d) would be added to require training in radiation safety, regulatory issues, and emergency procedures for the types of use for which an applicant seeks authorization. Paragraph (d) would apply to all pathways.

Section 35.51 - Training for an authorized medical physicist.

This section would be amended to modify the requirements that must be met as part of a specialty board certification process for the specialty board to be recognized by the Commission or an Agreement State. Instead of requiring that the certification process include the same criteria as the alternate pathway, paragraph (a) would be amended to provide separate

requirements for a specialty board's certification process. This process would include a requirement to pass an examination, administered by diplomates of the specialty board, which would evaluate knowledge and competency areas that are important to functioning as a medical physicist. The requirement for obtaining a preceptor statement would be removed from the requirements for recognition of specialty board certifications but would, instead, apply to each individual seeking recognition as an authorized medical physicist. A new paragraph (c) would be added to require training related to the type of use for which authorization is sought that includes "hands on" device operation, safety procedures, clinical use, and operation of a treatment planning system. Paragraph (c) would apply to all pathways. In addition, for the alternate pathway (paragraph (b)(1)), the acceptable areas of concentration for degrees would be expanded, and a requirement that the degree be from an accredited college or university would be added. Paragraph (b)(1) would also be amended to list the specific areas for which the individual needs to have training and work experience, instead of referring to other sections of Part 35. Requirements that training be received in an oncology facility would be generalized by removing the word oncology and "facility" would be pluralized to allow for training to be gained in more than one facility.

Section 35.55 - Training for an authorized nuclear pharmacist.

This section would be amended to modify the requirements that must be met as part of a specialty board certification process for the specialty board to be recognized by the Commission or an Agreement State. Instead of requiring that the certification process include the same criteria as the alternate pathway, paragraph (a) would be amended to provide separate requirements for a specialty board's certification process. This certification process would include a requirement to pass an examination, administered by diplomates of the specialty

board, which would evaluate knowledge and competency areas that are important to functioning as a nuclear pharmacist. The requirement for obtaining a preceptor statement would be removed from the requirements for recognition of specialty board certifications but would, instead, apply to each individual seeking recognition as an authorized nuclear pharmacist.

Section 35.57 - Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist.

Paragraph (a) would be amended to change "October 24, 2002," to the effective date of the final rule, if adopted.

Section 35.190 - Training for uptake, dilution, and excretion studies.

Paragraph (a) would be amended to modify the requirements that must be met as part of a specialty board certification process for the specialty board to be recognized by the Commission or an Agreement State for uses under § 35.100. A requirement would be added that candidates must pass an examination administered by diplomates of the specialty board. The requirement for obtaining a preceptor statement would be removed from the requirements for recognition of specialty board certifications but would, instead, apply to each individual seeking recognition as an authorized user under § 35.100. Additionally, paragraph (c)(1)(ii)(B) would be amended to reflect that the work experience must include performing quality control procedures on instruments used to determine the activity of dosages, a change from requiring only the calibration of these instruments.

Section 35.290 - Training for imaging and localization studies.

Paragraph (a) would be amended to modify the requirements that must be met as part of a specialty board certification process for the specialty board to be recognized by the Commission or an Agreement State for uses under § 35.200. A requirement would be added that candidates must pass an examination, administered by diplomates of the specialty board. The requirement for obtaining a preceptor statement would be removed from the requirements for recognition of specialty board certifications but would, instead, apply to each individual seeking recognition as an authorized user under § 35.200. Additionally, paragraph (c)(1)(ii)(B) would be amended to reflect that the work experience must include performing quality control procedures on instruments used to determine the activity of dosages, a change from requiring only the calibration of these instruments.

Section 35.390 - Training for use of unsealed byproduct material for which a written directive is required.

This section would be amended to modify the requirements that must be met as part of a specialty board certification process for the specialty board to be recognized by the Commission or an Agreement State for uses under § 35.900. Instead of requiring that the certification process include the same criteria as the alternate pathway, paragraph (a) would be amended to provide separate requirements for a specialty board's certification process. The requirement for obtaining a preceptor statement would be removed from the requirements for recognition of specialty board certifications but would, instead, apply to each individual seeking recognition as an authorized user under § 35.300. Paragraph (b)(1)(ii)(B) would be amended to reflect that the work experience must include performing quality control procedures on instruments used to determine the activity of dosages, a change from requiring only the calibration of these instruments. In addition, paragraphs (b)(1)(ii)(G)(3) and (4) would be amended to revise the

work experience requirement for individuals requesting AU status involving parenteral administration of dosages to limit it to those cases for which written directives are required.

Section 35.392 - Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries).

Paragraph (a) would be amended to include a statement that the recognized boards would be posted on the NRC's web page. Paragraph (c)(2)(ii) would be amended to modify the requirement that work experience must include performing quality control procedures on instruments used to determine the activity of dosages, a change from requiring only the calibration of these instruments.

Section 35.394 - Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries).

Paragraph (a) would be amended to include a statement that the recognized boards will be posted on the NRC's web page. Paragraph (c)(2)(ii) would be amended to modify the requirement that work experience must include performing quality control procedures on instruments used to determine the activity of dosages, a change from requiring only the calibration of these instruments.

Section 35.490 - Training for use in manual brachytherapy sources.

This section would be amended to modify the requirements that must be met as part of a specialty board certification process for the specialty board to be recognized by the Commission or an Agreement State. Instead of requiring that the certification process include the same criteria as the alternate pathway, paragraph (a) would provide separate requirements for a

specialty board's certification process. The requirement for obtaining a preceptor statement would be removed from the requirements for recognition of specialty board certifications but would, instead, apply to each individual seeking recognition as an authorized user under § 35.400. Additionally, paragraph (b)(2) would be amended to include the Royal College of Physicians and Surgeons of Canada in the listing of organizations that can provide approval of the formal training program.

Section 35.590 - Training for use of sealed sources for diagnosis.

Paragraph (a) would be amended to include a statement that recognized boards would be posted on the NRC's web page. Paragraph (b)(5) would be redesignated as paragraph (c) and would apply to both the certification and the alternate pathways. This revision would separate the requirement for training in the use of the device for the uses requested from the requirement for 8 hours of classroom and laboratory training in basic radionuclide handling techniques.

Section 35.690 - Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

This section would be amended to modify the requirements that must be met as part of a specialty board certification process for the specialty board to be recognized by the Commission or an Agreement State for uses under 35.600. Instead of requiring that the certification process include the same criteria as the alternate pathway, paragraph (a) would be amended to provide separate requirements for a specialty board's certification process. The requirement for obtaining a preceptor statement would be removed from the requirements for recognition of specialty board certifications but would, instead, apply to each individual seeking recognition as

an authorized user under § 35.600. Additionally, for the alternate pathway, paragraph (b)(2) would be amended to include the Royal College of Physicians and Surgeons of Canada in the listing of organizations that can provide approval of the formal training program. The requirement for experience in “radiation oncology” in paragraph (b)(2) would be modified to allow for experience in “radiation therapy.” A new paragraph (c) would be added to require training in device operation, safety procedures, and clinical use for the type(s) of use for which approval as an authorized user is sought. Paragraph (c) would apply to all pathways.

Changes to rule text: Substitute the following at appropriate points in the Rule Text.

(The NRC staff notes that conforming changes to §§ 35.13 and 35.14 would be required should the following changes to the proposed rule text be approved by the Commission.)

List of Subjects in 10 CFR Part 35

Byproduct material, Criminal penalties, Drugs, Health facilities, Health professions, Medical devices, Nuclear materials, Occupational safety and health, Radiation protection, Reporting and recordkeeping requirements.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 553; the NRC is proposing to adopt the following amendments to 10 CFR Part 35.

PART 35—MEDICAL USE OF BYPRODUCT MATERIAL

1. The authority citation for Part 35 continues to read as follows:

PART 35 - MEDICAL USE OF BYPRODUCT MATERIAL

AUTHORITY: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

2. In §35.50, paragraphs (a) and (c) are revised, and paragraph (d) is added to read as follows:

§ 35.50 Training for Radiation Safety Officer.

* * * * *

(a) Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State. (Specialty Boards whose certification process has been recognized by the Commission or an Agreement State will be posted on the NRC's web page.) To be recognized, a specialty board shall require all candidates for certification to:

(1) Hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science;

(2) Have 5 or more years of professional experience in health physics (graduate training may be substituted for no more than 2 years of the required experience) including at least three years in applied health physics; and

(3) Pass an examination administered by diplomates of the specialty board, which evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry; or

(b) * * *

(c) Has obtained written certification, signed by a preceptor Radiation Safety Officer, that the individual has satisfactorily completed the requirements in paragraph (a) or (b) of this section and has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee; or

(d) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license, or a medical physicist who has been certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State under § 35.51(a) and has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual has Radiation Safety Officer responsibilities; and

(e) Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by an authorized medical physicist, authorized user, authorized nuclear pharmacist, or radiation safety officer, as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval.

3. In §35.51, paragraphs (a) and (b) are revised, and paragraph (c) is added to read as follows:

§ 35.51 Training for an authorized medical physicist.

* * * * *

(a) Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State. (Specialty Boards whose certification process has been recognized by the Commission or an Agreement State will be posted on the NRC's web page.) To be recognized, a specialty board shall require all candidates for certification to:

(1) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

(2) Have 2 years of full-time practical training and/or supervised experience in medical physics --

(i) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Commission or an Agreement State, or

(ii) In clinical radiation facilities providing high energy, external beam therapy and brachytherapy services under the direction of physicians who meet the requirements for authorized users in §§ 35.490 or 35.690;

(3) Pass an examination, administered by diplomates of the specialty board, which assesses knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery; or

(b)(1) Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; and has completed 1 year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the type(s) of use modalities for which the individual is seeking authorization. This training and work experience must be conducted in clinical radiation facilities that provide high energy, external beam therapy and brachytherapy services and must include:

(i) Performing sealed source leak tests and inventories;

(ii) Performing decay corrections;

(iii) Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

(iv) Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

(c) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraph (a) or (b)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written certification must be signed by a preceptor authorized medical physicist who meets the requirements in § 35.51 or equivalent Agreement State requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status; and

(d) Has training for the type(s) of use in the modalities for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an authorized medical physicist authorized for the type(s) of use for which the individual is seeking authorization.

4. In § 35.55, paragraph (a) is revised and paragraph (c) is added to read as follows:

§ 35.55 Training for an authorized nuclear pharmacist.

* * * * *

(a) Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State. (Specialty Boards whose certification process has been recognized by the Commission or an Agreement State will be posted on the NRC's web page.) To be recognized, a specialty board shall require all candidates for certification to:

(1) Have graduated from a pharmacy program accredited by the American Council On Pharmaceutical Education (ACPE) or have passed the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination;

(2) Hold a current, active license to practice pharmacy;

(3) Provide evidence of having acquired at least 4,000 hours of training/experience in nuclear pharmacy practice. Academic training may be substituted for no more than 2,000 hours of the required training and experience;

(4) Pass an examination in nuclear pharmacy administered by diplomates of the specialty board, which assesses knowledge and competency in procurement, compounding, quality assurance, dispensing, distribution, health and safety, radiation safety, provision of information and consultation, monitoring patient outcomes, research and development; or

* * * * *

(b) * * *

(c) Has obtained written certification, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in paragraph (a) or (b) of this section and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

§ 35.57 [Amended]

5. In § 35.57, replace both references to "October 24, 2002" with "[insert effective date of final rule]".

6. In § 35.190, paragraphs (a) and (c)(1)(ii)(B) are revised and paragraph (d) is added to read as follows:

§ 35.190 Training for uptake, dilution, and excretion studies.

* * * * *

(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State. (Specialty Boards whose certification process has been recognized by the Commission or an Agreement State will be posted on the NRC's web page.) To be recognized, a specialty board shall require all candidates for certification to:

(1) Meet the requirements in paragraph (c)(1) of this section;

(2) Pass an examination, administered by diplomates of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

* * * * *

(c) * * *

(1) * * *

(ii) * * *

(B) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

* * * * *

(d) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in §§ 35.190, 35.290, or 35.390 or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (a) or (c)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under § 35.100.

* * * * *

7. In § 35.290, paragraphs (a) and (c)(1)(ii)(B) are revised and paragraph (d) is added to read as follows:

§ 35.290 Training for imaging and localization studies.

* * * * *

(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State. (Specialty Boards whose certification process has been recognized by the Commission or an Agreement State will be posted on the NRC's web page.) To be recognized, a specialty board shall require all candidates for certification to:

(1) Satisfy the requirements in paragraph (c)(1) of this section;

(2) Pass an examination, administered by diplomates of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

* * * * *

(c) * * *

(1) * * *

(ii) * * *

(B) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

* * * * *

(d) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in §§ 35.290 or 35.390 or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (a) or (c)(1) of this section

and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under §§ 35.100 and 35.200.

* * * * *

8. In § 35.390 paragraph (a), paragraphs (b)(1)(ii)(B), and (b)(1)(ii)(G)(3) and (4) are revised and paragraph (c) is added to read as follows:

§ 35.390 Training for use of unsealed byproduct material for which a written directive is required.

* * * * *

(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State. (Specialty Boards whose certification process has been recognized by the Commission or an Agreement State will be posted on the NRC's web page.) To be recognized, a specialty board shall require all candidates for certification to:

(1) Successfully complete a minimum of three years of residency training in a radiation oncology or nuclear medicine training program or a program in a related medical specialty that includes 700 hours of training and experience as described in paragraph (b)(1) of this section. Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association;

(2) Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed byproduct material; or

(b) * * *

(1) * * *

(ii) * * *

(B) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

* * * * *

(G) * * *

(3) Parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV, for which a written directive is required; and/or

(4) Parenteral administration of any other radionuclide for which a written directive is required; and

(c) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraph (a) or (b)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under § 35.300. The written certification must be signed by a preceptor authorized user who meets the requirements in § 35.390(a), § 35.390(b), or equivalent Agreement State requirements. The preceptor authorized user, who meets the requirements in § 35.390(b), must have experience in administering dosages in the same dosage category or categories (i.e., § 35.390(b)(1)(ii)(G)(1), (2), (3), or (4)) as the individual requesting authorized user status.

* * * * *

9. In § 35.392, paragraphs (a) and (c)(2)(ii) are revised and paragraph (d) is added to read as follows:

§ 35.392 Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries).

* * * * *

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (c)(1) and (2) of this section and whose certification has been recognized by the Commission or an Agreement State. (Specialty Boards whose certification process has been recognized by the Commission or an Agreement State will be posted on the NRC's web page.) or

* * * * *

(c) * * *

(2) * * *

(ii) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

* * * * *

(d) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraphs (a) or (c)(1) and (c)(2) of this section and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under § 35.300. The written certification must be signed by a preceptor authorized user who meets the requirements in § 35.390(a), § 35.390(b), § 35.392, § 35.394, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirement in § 35.390(b), must have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(1) or (2).

10. In § 35.394, paragraphs (a) and (c)(2)(ii) are revised and paragraph (d) is added to read as follows:

§ 35.394 Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries).

* * * * *

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (c)(1) and (2) of this section and whose certification has been recognized by the Commission or an Agreement State. (Specialty Boards whose certification process has been recognized by the Commission or an Agreement State will be posted on the NRC's web page.) or

* * * * *

(c) * * *

(2) * * *

(ii) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

* * * * *

(d) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraphs (a) or (c)(1) and (c)(2) of this section and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under § 35.300. The written certification must be signed by a preceptor authorized user who meets the requirements in § 35.390(a), § 35.390(b), § 35.394, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirements in § 35.390(b), must have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(2).

11. In § 35.490, paragraphs (a) and (b)(2) are revised and paragraph (c) is added to read as follows:

§ 35.490 Training for use of manual brachytherapy sources.

* * * * *

(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State. (Specialty Boards whose certification process has been recognized by the Commission or an Agreement State will be posted on the NRC's web page.) To be recognized, a specialty board shall require all candidates for certification to:

(1) Successfully complete a minimum of three years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association;

(2) Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of high and low dose-rate brachytherapy; or

(b) * * *

(2) Has completed 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in § 35.490 or equivalent Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained

concurrently with the supervised work experience required by paragraph (b)(1)(ii) of this section;
and

(c) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in § 35.490 or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraphs (a) or (b)(1) and (b)(2) of this section and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under § 35.400.

* * * * *

12. In § 35.590, paragraphs (a) and (b) are revised and paragraph (c) is added to read as follows:

§ 35.590 Training for use of sealed sources for diagnosis.

* * * * *

(a) Is certified by a specialty board whose certification process includes all of the requirements in paragraphs (b) and (c) of this section and whose certification has been recognized by the Commission or an Agreement State. (Specialty Boards whose certification process has been recognized by the Commission or an Agreement State will be posted on the NRC's web page.); or

(b) Has completed 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include --

- (1) Radiation physics and instrumentation;
- (2) Radiation protection;
- (3) Mathematics pertaining to the use and measurement of radioactivity;
- (4) Radiation biology; and

(c) Has completed training in the use of the device for the uses requested.

13. In § 35.690, paragraphs (a), (b)(2), and (b)(3) are revised and paragraph (c) is added to read as follows:

§ 35.690 Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

* * * * *

(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State. (Specialty Boards whose certification process has been recognized by the Commission or an Agreement State will be posted on the NRC's web page.) To be recognized, a specialty board shall require all candidates for certification to:

(1) Successfully complete a minimum of three years of residency training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association;

(2) Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, high and low dose-rate brachytherapy, and external beam therapy; or

(b) * * *

(2) Has completed 3 years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in § 35.690 or equivalent Agreement State requirements, as part of a formal training program approved by the Residency Review

Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (b)(1)(ii) of this section; and

(c) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraphs (a) or (b)(1) and (b)(2) of this section and has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written certification must be signed by a preceptor authorized user who meets the requirements in § 35.690 or equivalent Agreement State requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status; and

(d) Has received training in device operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought. This training requirement may be satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the type(s) of use for which the individual is seeking authorization.